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MEDLEN & CARROLL, LLP			WORLEY, CATHY KINGDON	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>		<b>Application No.</b>	<b>Applicant(s)</b>
10/751,235		DELLAPENNA ET AL.	
<b>Examiner</b>	<b>Art Unit</b>		
CATHY K. WORLEY	1638		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

- 1) Responsive to communication(s) filed on 17 February 2009.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

- 4) Claim(s) 1-8, 10-17 and 21-36 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-8, 10-17, and 21-36 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

**DETAILED ACTION**

1. The amendment filed Feb. 17, 2009, has been entered.

2. Claims 9, 18-20, and 37 have been cancelled.

Claims 1-8, 10-17, and 21-36 are pending and are examined in the present Office Action.

***Objections and Rejections that are Withdrawn***

3. The rejection of claim 36 under 35 USC 112, 2<sup>nd</sup> paragraph, is withdrawn in light of the Applicant's amendments to the claims.

4. The rejection of claims 11-13, 16, 17, 21-30, and 32-34 under 35 U.S.C. 101 is withdrawn in light of the Applicant's arguments. The Examiner questions the credibility of the asserted utility, however, this is covered under the enablement rejection with references to support the Examiner's reasoning for questioning the asserted utility; and therefore, if the Applicant can provide evidence that the claimed nucleic acids can alter lutein in a wild type plant or produce an active enzyme in a prokaryotic cell or a yeast cell, then both the enablement rejection and the utility rejection would be withdrawn. Therefore, the rejections are redundant and the Examiner will withdraw the rejection under 35 USC 101.

***Claim Objections***

5. Claims 30-32, 34, and 35 are objected to because of the following informalities: the amended claims recite "a polypeptide listed as SEQ ID NO:4", and therefore the article "a" disagrees with the fact that SEQ ID NO:4 discloses a single polypeptide sequence. The Applicant is advised to replace "a" with - - the - -. Appropriate correction is requested.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 32 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. All dependent claims are included in this rejection.

Claim 32 has been amended to recite "a polypeptide listed as SEQ ID NO:4 and SEQ ID NO:1", and this is confusing because "polypeptide" is singular, but it is followed by two separate polypeptide sequences. It is unclear if this means either

SEQ ID NO:4 or SEQ ID NO:1 or if this means a fusion protein that comprises both sequences.

7. Claim 36 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 36 has been amended to include the recitation “that comprises 12.5 fold higher level of lutein as compared to lutein produced in a wild type plant tissue”. The Applicant pointed to page 45 for support for this language, however, page 45 discloses that mutant plants had 8% of the lutein compared to wild-type plants. When these mutant plants were transformed with the nucleic acid of the instant invention, the amount of lutein was restored to wild-type levels. Therefore, the 12.5% increase was not relative to a wild type plant as the amended claim recites. The 12.5% increase was relative to a *Lut1* mutant *Arabidopsis* plant. Therefore the recitation of recitation “that comprises 12.5 fold higher level of lutein as compared to lutein produced in a wild type plant tissue” introduces NEW MATTER.

8. Claims 1-8, 10-17, and 21-36 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s)

contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Applicant's arguments in the response filed on Feb. 17, 2009, were fully considered but were not found to be persuasive.

Claims 1-8, 10-17, and 21-36 are broadly drawn to expression vectors, nucleic acids, transgenic plants and seeds, and methods comprising a nucleic acid sequence encoding a polypeptide at least 72% identical to SEQ ID NO:4 and having monooxygenase P450 activity.

The nature of the invention is molecular biological approaches for using a nucleic acid discovered by complementing a mutant.

The specification discloses that a nucleic acid comprising SEQ ID NO:5 was identified by its ability to complement the *lut1* mutation in *Arabidopsis* (see page 102 lines 6-9 and Figure 19a). This nucleic acid encodes the amino acids identified as SEQ ID NO:4 (see Figure 19a). A subsequence of SEQ ID NO:4 is identified as SEQ ID NO:1 (see Figure 18). The specification discloses that bioinformatics analyses suggests the polypeptide of SEQ ID NO:4 is a cytochrome P450 enzyme and comprises an oxygen binding pocket consensus sequence (SEQ ID NO:12), a heme-binding cysteine motif (SEQ ID NO:14), a chloroplast targeting peptide (SEQ ID NO:11), and a transmembrane domain (SEQ ID NO:10), (see pages 102-103 and Figure 22).

The specification does not disclose any enzyme assays showing that the protein encoded by SEQ ID NO:5 has a specific enzymatic function. Transformation of the *lut1* mutant *Arabidopsis* plant with SEQ ID NO:5 complements the mutant phenotype and therefore, either directly or indirectly, provides  $\beta$ -ring hydroxylase and  $\epsilon$ -ring hydroxylase activity (see page 103-104 and Figure 17). However, subsequent experimental work was unsuccessful in providing an assay for enzymatic function (see Tian et al PNAS (2004) Vol. 101, pp. 402-407). Tian et al teach that initial attempts to express and assay LUT1 protein in yeast were unsuccessful (see Tian et al, page 405, left column), and expression in bacteria is highly unlikely to work given the problems of expression eukaryotic membrane proteins in prokaryotic systems (see Hannig et al TIBTECH (1998) Vol. 16, "focus", see second-to-last page, right column). Therefore, one of skill in the art would not know how to use the nucleic acids and vectors for prokaryotic or yeast expression (claims 11 and 14 are specifically not enabled for these reasons). The only function demonstrated is the ability to complement the *lut1* mutant *Arabidopsis* plant which yields a very expensive, transgenic, weed that has the same characteristics as a corresponding wild-type weed.

The instant application speculates that SEQ ID NO:5 encodes a cytochrome P450 enzyme with  $\beta$ -ring hydroxylase and  $\epsilon$ -ring hydroxylase activity that is involved in carotenoid biosynthesis, however, even if this hypothesis is true, multiple enzymes are involved in this pathway, and it is highly unpredictable what

phenotype would result from overexpression of only one of the enzymes involved. The prior art teaches that metabolic engineering of biosynthetic pathways is highly unpredictable (see Stephanopoulos et al TIBTECH (1993), Vol. 11, pp. 392- 396). It is possible the required enzymes may have to be present in stoichiometric quantities, or there could be feedback regulation mechanisms that are complex. It would require undue experimentation on the part of one of skill in the art to determine the results of expressing SEQ ID NO:5 in a plant, and to elucidate what other steps (if any) would be required to generate a useful plant.

Given this unpredictability and given that the specification in the instant application has not provided any working examples of expression of SEQ ID NO:5 in a healthy wild-type plant to demonstrate there is an effect on carotenoid metabolism (other than complementing a mutant which is deficient in the identical enzyme), one of skill in the art would not know how to use the claimed expression vectors, nucleic acids, transgenic plants and seeds, and the methods recited in claims 28-32 are not enabled.

#### POTENTIAL SCOPE OF ENABLEMENT

Even if the Applicant can provide support for a use of SEQ ID NO:5, the enablement would not be extended to the entire genus of molecules encompassed by these claims. The claims encompass nucleic acids encoding polypeptides with as little as 72% identity to SEQ ID NO:4, and one of skill in the art would not know how to use any such nucleic acids. The specification does not disclose any nucleic

acid other than SEQ ID NO:5 that encodes a polypeptide at least 72% identical to SEQ ID NO:4 that has been shown to have the function of producing zeinxanthin and the function of complementing the *lut1* mutation in *Arabidopsis*, and there are multitudes of nucleic acids encompassed by this recitation. Even if there were some guidance on how to use a nucleic acid encoding  $\epsilon$ -ring hydroxylase and  $\beta$ -ring hydroxylase activity that is involved in carotenoid biosynthesis, there is no guarantee that one of skill in the art would be successful in expressing a polypeptide with as little as 72% identity to SEQ ID NO:4 to produce a recombinant protein with monooxygenase P450 activity. The specification has not provided any working example to demonstrate that a polypeptide having as little as 72% identity and comprising SEQ ID NO:1, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, and SEQ ID NO:14 would be capable of catalyzing any reaction at all. These domains, put together, have not been shown to be sufficient for enzymatic activity or the desired carotenoid biosynthesis function.

Given the breadth of the claims, the unpredictability in the art, and the lack of working examples, it would require undue experimentation on the part of one of skill in the art to make and use the invention as claimed.

#### APPLICANT'S ARGUMENTS

The Applicant argues that the specification teaches that expressing SEQ ID NO:4 resulted in a 12.5 fold increase in the level of the lutein product of the carotenoid pathways from the 8% of the amount of lutein in wild-type *Arabidopsis*

to 100% of wild type levels (see third paragraph on page 14 of the response) and that these data were published in a peer reviewed article by Tian et al (see pages 14-15 of the response).

This is not persuasive, however, because these data merely demonstrate that mutant *Lut1* *Arabidopsis* plants can be restored to wild-type phenotype by expression of SEQ ID NO:4. This shows that SEQ ID NO:4 is necessary for producing a normal level of lutein, but it does not show that one can increase the level of lutein above and beyond normal levels by expressing SEQ ID NO:4 in a wild-type plant. As the Examiner has pointed out, one of skill in the art would not know how to use a very expensive transgenic weed that has a normal phenotype with regard to the levels of lutein, and this is the only use for the claimed nucleic acids that has been demonstrated.

The Applicant argues that the reference by Stephanopoulos et al was published 11 years before the instant application's filing date and that two issued US Patents (6,524,811 and 6,642,021) have claims that recite expressing a DNA sequence encoding one enzyme in the carotenoid biosynthetic pathway to alter levels of one or more carotenoid products and two pre-grant publications (US 2002/0102631 and US 2002/0086380) teach expression of a DNA sequence encoding one enzyme that alters the levels of one or more carotenoid products (see pages 15-16 of the response).

This is not persuasive, however, because there is no evidence to demonstrate that the teachings of Stephanopoulos et al are no longer valid. The field of metabolic engineering continues to be very unpredictable for complicated pathways that comprise multiple enzymes and multiple substrates, such as the carotenoid pathway. With regard to the issued patents and pre-grant publications, in each of these cases, the nucleic acids were shown to encode functional enzymes by successful expression in *E. coli*. In US Patent No. 6,524,811, the nucleic acids were shown to produce functional enzymes when expressed in *E. coli* (see column 8). In US Patent No. 6,642,021, the nucleic acids were shown to produce functional enzymes when expressed in *E. coli* (see column 17). In US 2002/0102631, the nucleic acids were shown to produce functional enzymes when expressed in *E. coli* (see page 9, right column, paragraph 0121). In US 2002/0086380, the nucleic acids were shown to produce functional enzymes when expressed in *E. coli* (see page 5, left column, paragraph 0066). Therefore, the fact patterns in these other cases are substantially different from the instant application, because these other applications have demonstrated expression of the functional enzyme in *E. coli*.

There is no such data in the instant application to demonstrate successful production of a functional protein in *E. coli*. The Examiner has provided references that teach unsuccessful attempts at expression of the claimed protein in yeast, and unpredictability for expression in *E. coli*. Tian et al teach that initial attempts to express and assay LUT1 protein in yeast were unsuccessful (see Tian et al, page

405, left column), and expression in bacteria is highly unlikely to work given the problems of expression eukaryotic membrane proteins in prokaryotic systems (see Hannig et al TIBTECH (1998) Vol. 16, “focus”, see second-to-last page, right column). It is noted that the unsuccessful attempt by Tian et al was directed at expression of the exact same protein recited in the instant claims (SEQ ID NO:4). The Applicant provided a post-filing reference that further supports the unpredictability on *E. coli*; Quinlan et al state that only a subset of P450 enzymes function in *E. coli* and the heterologous bacterial system is not necessarily a feasible approach (see page 148, left column).

The Applicant argues that they have taught enzyme assays for  $\beta$ -hydroxylase and  $\epsilon$ -hydroxylase activity (see section “B” on page 16 of the response). This is not persuasive, however, because the issue is not whether or not there is an available assay for such activity, the issue is whether or not one of skill in the art can produce a functional enzyme in *E. coli* or yeast cells, or, if the enzyme is produced in a plant, whether or not it will alter the amount of lutein in the plant. The Examiner agrees that there are assays available to measure  $\beta$ -hydroxylase and  $\epsilon$ -hydroxylase activity. The Examiner does not agree that one can produce a function enzyme comprising SEQ ID NO:4 in an *E. Coli* or yeast cell, and the Examiner does not agree that producing recombinant SEQ ID NO:4 will have an effect on the amount of lutein in a wild-type plant.

The Applicant argues that there are several successful prior art reports of expressing P450 enzymes in yeast (see page 17 of the response). This is not persuasive, however, because the claims are not directed to any of these other P450 enzymes, the claims are directed to nucleic acids encoding SEQ ID NO:4. The fact remains that the elected protein (SEQ ID NO:4) could not be expressed successfully in yeast as disclosed in the peer-reviewed article by Tian et al. The Applicant argues that these were “initial” attempts, and this does not negate enablement since the mere possibility of inclusive or inoperative subject matter does not prevent allowance of broad claims (see first paragraph on page 17). This is not persuasive, because the unsuccessful initial attempt has not been followed up by any successful attempts at expression of SEQ ID NO:4, and the potential inoperative embodiment is not due to the broad range of the claims; in this case the inoperative embodiment is SEQ ID NO:4, itself, with no changes made. The Examiner has repeatedly invited the Applicant to provide data showing any successful expression of this enzyme, and the Applicant has provided only arguments.

The Applicant argues that the reference relied on by the Examiner regarding unpredictability for expression of membrane proteins in *E. coli* (Hannig et al) was published 6 years prior to the filing date of the instant application (see second paragraph on page 18 of the response). This is not persuasive, however, because the Applicant provided a post-filing reference (Quinlan et al) published 3 years after the filing date of the instant application, and this reference reinforces the

unpredictability of expression of P450 enzymes in *E. coli*. Quinlan et al state that only a subset of P450 enzymes function in *E. coli* and the heterologous bacterial system is not necessarily a feasible approach (see page 148, left column).

Furthermore, Quinlan et al utilized a complicated system of expressing SEQ ID NO:16 in a pCOLADuet vector in BL21 (DE3) cells along with a second plasmid encoding the *Arabidopsis lycopene ε cyclase* (see page 148, right column).

Therefore, the field did not advance substantially after the reference by Hannig that the Examiner relied upon.

The Applicant argues that there are several examples of successful expression of P450 enzymes in prokaryotes such as *E. coli* (see page 18 of the response). This is not persuasive, however, because the claims are not directed to any of these other P450 enzymes, the claims are directed to nucleic acids encoding SEQ ID NO:4. The fact remains that the elected protein (SEQ ID NO:4) could not be expressed successfully in yeast as disclosed in the peer-reviewed article by Tian et al, and there are no reports of successful expression of SEQ ID NO:4 in *E. coli* or any other prokaryote. The Examiner has repeatedly invited the Applicant to provide data showing any successful expression of this enzyme, and the Applicant has provided only arguments.

The Applicant argues that the Examiner's insistence of a showing that expression of SEQ ID NO:5 in a wild-type plant has an effect on carotenoid metabolism is in error because none of the claims require that a plant transformed

with the recited sequences be a wild-type plant (see first paragraph on page 19 of the response). This is not persuasive, however, because the Examiner is pointing out that the ability to complement the mutant phenotype of the *lut1* mutant is not enough to provide enablement because one of skill in the art would not know how to use this complemented mutant. It is merely a transgenic mutant *Arabidopsis* plant with the same phenotype of a wild-type *Arabidopsis* plant, and therefore, one of skill in the art would only know how to replicate all the steps of transforming the *lut1* mutant to express SEQ ID NO:5 (which encodes SEQ ID NO:4), and end up with an *Arabidopsis* plant that is no different than a wild-type *Arabidopsis* plant. This is similar to suggesting that one can use a transgenic mouse to feed a snake. If the recited transgene has no useful effect on the host in which it is expressed, then one would not know how to use it.

The Applicant argues that the data in Example 5 beginning on page 103 of the specification demonstrate that expression of SEQ ID NO:5 that encodes SEQ ID NO:4 resulted in a 12.5 fold increase in the level of lutein produced by the plants (see second paragraph on page 19 of the response). This is not persuasive, however, because these are the data that demonstrate restoring the wild-type phenotype to the *lut1* mutant *Arabidopsis* plants. The mutant plants had 12.5-fold lower lutein compared to wild-type (reported as 8% of wild-type, which is 12.5-fold lower than 100%). When the mutant plants were transformed with SEQ ID NO:5, they

produced the same amount of lutein as wild-type, and therefore, they produced 12.5 fold higher than non-transformed *lut1* mutants.

The Applicant argues that the Examiner's insistence of a guarantee is improper (see first paragraph on page 20 of the response). The Examiner apologizes for using the word "guarantee". The Examiner is aware that there is no requirement of a guarantee. However, in light of the published account of an unsuccessful attempt to produce functional enzyme in yeast (see Tian et al), and in light of the published account stating that only a subset of P450 enzymes function in *E. coli* and the heterologous bacterial system is not necessarily a feasible approach (see Quinlan et al), and in light of the only data in plants demonstrating lutein levels that are no higher than wild-type, the Examiner believes there is a good reason to believe that expression of SEQ ID NO:4 will not work.

The Applicant argues that the Examiner's dismissal of the evidence of Quinlan et al is in error (see second paragraph on page 20 of the response). The Applicant argues that SEQ ID NO:16 (which is the homolog from rice) is 78% identical to the elected SEQ ID NO:4 (which is the clone from *Arabidopsis*), and therefore it falls within the scope of the claimed 72% identity. This is not persuasive, however, because SEQ ID NO:16 was not the elected sequence; the Applicant elected SEQ ID NO:4 for prosecution. The publication by Quinlan et al was a post-filing publication, therefore, at the time of filing, one of skill in the art would not have known that they should utilize a sequence from rice that is 78%

identical to the recited sequence of SEQ ID NO:4. Since attempts to produce functional enzyme comprising SEQ ID NO:4 in yeast were unsuccessful (see Tian et al), and the data by Quinlan et al are post-filing data, one of skill in the art would not have known to abandon the *Arabidopsis* clone and pursue the rice clone that has 78% identity to the elected and recited sequence. It is noted that only the broadest claims encompass the rice homolog of SEQ ID NO:16; claims 10, 15-17, 21-24, and 26-36 exclude the rice homolog of SEQ ID NO:16.

The Applicant argues that Quinlan's use of the pCOLADuet vector along with a second plasmid encoding the *Arabidopsis* lycopene  $\epsilon$  cyclase does not constitute undue experimentation because the art typically engages in such experimentation and the vectors are commercially available (see paragraph bridging pages 20-21 of the response). This is not persuasive, however, because there is no suggestion in the instant specification that the *Arabidopsis* lycopene  $\epsilon$  cyclase should be co-expressed with the instant SEQ ID NO:4, therefore, this is an enabling feature of the post-filing experiments that was not available at the time of filing.

The Applicant argues that the specification provides methods for expressing the recited sequences and the prior art is replete with a plethora of systems for expression of P450 membrane proteins in yeast and prokaryotic cells (see page 21 of the response). This is not persuasive, however, because none of the methods taught in the specification or taught in the prior art were shown to be successful for

producing functionally active SEQ ID NO:4; and the art specifically teaches that attempts at expressing SEQ ID NO:4 in yeast were not successful (see Tian et al.).

The Examiner has repeatedly invited the Applicant to provide data showing any successful expression of this enzyme, and the Applicant has provided only arguments.

9. All claims remain rejected.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHY K. WORLEY whose telephone number is (571)272-8784. The examiner has a variable schedule but can normally be reached on M-F 10:00 - 4:00, with additional variable hours before 10:00 and after 4:00 with variable hours before 10:00 and after 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Cathy K. Worley/  
Primary Examiner, Art Unit 1638